

CPE-JLS

The opinion in support of the decision being entered today was <u>not</u> written for publication and is <u>not</u> binding precedent of the Board.

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Paper No. 48

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MANFRED BOHN, KARL THEODOR KRAEMER, and ASTRID MARKUS

Application No. 09/077,194

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U.S. PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

DECISION ON REQUEST FOR REHEARING

Before WINTERS, MILLS, and GREEN, <u>Administrative Patent Judges</u>.
WINTERS, <u>Administrative Patent Judge</u>.

ON REQUEST FOR REHEARING

Pursuant to the provisions of 37 CFR § 41.52, applicants request rehearing of our decision mailed September 15, 2004 (Paper No. 46), vacating the examiner's final rejections of claims 38 through 42, 48, and 53 through 66; and entering new grounds of rejection under 37 CFR § 41.50(b).

On rehearing, applicants' main argument is that we have misinterpreted the claim language "a method of treating a human or animal patient in need of treatment for seborrheic dermatitis." According to applicants, (1) we have interpreted the language

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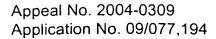
too broadly; (2) the claim language does not "read on" treating mere symptoms of seborrheic dermatitis (Request for Rehearing, paragraph bridging pages 2 and 3); and (3) the appealed claims should be construed to require an <u>intent to treat</u> a human or animal patient suffering from seborrheic dermatitis, or to require administering applicants' compositions to patients suffering from seborrheic dermatitis with the <u>intent</u> to cure the underlying condition (<u>id.</u>, page 4). We disagree.

Jansen Distinguished

In espousing their position, applicants rely principally on <u>Jansen v. Rexall</u>

<u>Sundown, Inc.</u>, 342 F.3d 1329, 68 USPQ2d 1154 (Fed. Cir. 2003). That reliance is misplaced.

In <u>Jansen</u>, appeal was taken from the final decision of the United States District Court for the Southern District of Indiana granting summary judgment that Rexall Sundown, Inc. has not infringed Jansen's U.S. Patent Number 4,945,083. In affirming that decision, the Federal Circuit applied "the mode of claim interpretation . . . used by courts in litigation, when interpreting the claims of issued patents in connection with determinations of infringement or validity." <u>In re Zletz</u>, 893 F.2d 319, 321, 13 USPQ2d 1320, 1321 (Fed. Cir. 1989). This is not, however, "the mode of claim interpretation . . . applicable during prosecution of a pending application before the PTO." <u>Id.</u> at 321, 13 USPQ2d at 1322.



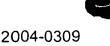
As stated in In re Zletz, 893 F.2d at 321-22, 13 USPQ2d 1322:

During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow. When the applicant states the meaning that the claim terms are intended to have, the claims are examined with that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art. See In re Prater, 415 F.2d 1393, 1404-05, 56 CCPA 1381, 162 USPQ 541, 550-51 (1969) (before the application is granted, there is no reason to read into the claim the limitations of the specification). The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breath of language explored, and clarification imposed. Burlington Industries, Inc. v. Quigg, 822 F.2d 1581, 1583, 3 USPQ2d 1436, 1438 (Fed.Cir.1987; In re Yamamoto, 740 F.2d 1569, 1571, 222 USPQ 934, 936 (Fed.Cir.1984). The issued claims are the measure of the protected right. United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 232, 63 S.Ct. 165, 167, 87 L.Ed. 232, 55 USPQ 381, 383-84 (1942)(citing General Electric Co. v. Wabash Appliance Corp., 304 U.S. 364, 369, 58 S.Ct. 899, 901-02, 82 L.Ed. 1402, 37 USPQ 466, 468-69 (1938). An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.

Applicants' position to the contrary, notwithstanding, <u>Jansen</u> does not set forth a rule of claim interpretation applicable during prosecution of pending applications before the PTO. During patent examination, applicants' claims "must be interpreted as broadly as their term reasonably allow" and "there is no reason to read into the claim[s] the limitations of the specification."

As stated in <u>Jansen</u>, 342 F.3d at 1333, 68 USPQ2d at 1158, the court's conclusion respecting the meaning of claim language "is bolstered by an analysis of the prosecution history." The court stated that:

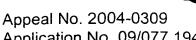
In this case, the "treating or preventing macrocytic-megaloblastic anemia" phrase and the "to a human in need thereof" phrase were added to gain



allowance of the claims after almost twenty years of repeatedly unsuccessful attempts to gain allowance of claims without those phrases. We must therefore give them weight, for the patentability of the claims hinged upon their presence in the claim language. See Smith v. Magic City Kennel Club, Inc., 282 U.S. 784, 790, 51 S.Ct. 291, 75 L.Ed. 707 (1931) ("The applicant[,] having limited his claim by amendment and accepted a patent, brings himself within the rules that if the claim to a combination be restricted to specified elements, all must be regarded as material, and that limitations imposed by the inventor, especially such as were introduced into an application after it had been persistently rejected. must be strictly construed against the inventor and looked upon as disclaimers."). Furthermore, because both phrases were added simultaneously to overcome the same rejection, they should be read together, meaning that the word "thereof" in the phrase "to a human in need thereof" should be construed to refer to the treatment or prevention of macrocytic-megaloblastic anemia. Finally, that "need" must be recognized and appreciated, for otherwise the added phrases do not carry the meaning that the circumstances of their addition suggests that they carry. In other words, administering the claimed vitamins in the claimed doses for some purpose other than treating or preventing macrocyticmegaloblastic anemia is not practicing the claim method, because Jansen limited his claims to treatment or prevention of that particular condition and those who need such treatment or prevention. Thus, the '083 patent claims are properly interpreted to mean that the combination of folic acid and vitamin B₁₂ must be administered to a human with a recognized need to treat or prevent macrocytic-megaloblastic anemia.

Id. at 1333-34, 68 USPQ2d at 1158 (emphasis added). But no such facts have been established here. Applicants do not point to prosecution history in this case, similar to that outlined in <u>Jansen</u>, which would give rise to a narrow claim construction based on estoppel or disclaimer.

Furthermore, the claims in <u>Jansen</u> are restricted to methods of treating or preventing macrocytic-megaloblastic anemia in humans; and "the issue reduces to whether such a human must know that he is in need of either treatment or prevention of that condition." <u>Jansen</u>, 342 F.3d at 1333, 68 USPQ2d at 1157. The claims before us,



however, are drawn to "a method of treating a human or animal patient in need of treatment for seborrheic dermatitis" (emphasis added).

In conclusion, <u>Jansen</u> is distinguishable from the present case because (1) Jansen was decided on appeal from a District Court decision granting summary judgment in a patent infringement suit, where a different mode of claim interpretation applied; (2) applicants do not point to prosecution history here, similar to that outlined in Jansen, which would give rise to a narrow claim construction; and (3) the method claims in <u>Jansen</u> are restricted to human subjects compared with the broader claims before us, drawn to "a method of treating a human or animal patient in need of treatment for seborrheic dermatitis."

Intent to Treat vs. Intent to Cure

Applicants argue that their claimed invention is not anticipated by, or obvious from, the cited prior art because the prior art does not disclose that compositions recited in the appealed claims are administered to patients suffering from seborrheic dermatitis with the intent to cure the underlying condition (Request for Rehearing, paragraph bridging pages 4 and 5). That argument, however, is predicated on faulty claim construction which relies on a limitation not present in applicants' claims.

Based on our review of the specification, the only passage which refers to a "cure" of seborrheic dermatitis appears at page 2, lines 1 through 4:

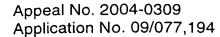
In comparison to ketoconazole, the substances according to the invention - even after only a short topical contact time - concentrate rapidly in the skin layers which are relevant for fungal growth and thus contribute to a rapid cure. (Emphasis added).

It is improper, however, to import limitations from the specification into claims in a pending application. See, In re Zletz, 893 F.2d at 1321, 13 USPQ2d 1322 (Before the application is granted, there is no reason to read into the claim the limitations of the specification). The claims are the measure of the protected right, and an essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. (Id.). Here, applicants' claims are couched in terms of treating ("a method of treating a . . . patient in need of treatment for seborrheic dermatitis"). Manifestly, treating is not the same a curing, and we shall not construe applicants' claims as requiring an "intent to cure the underlying condition."

Applicants' argument that the appealed claims should be construed to require an intent to treat a human or animal patient suffering for seborrheic dermatitis (Request for Rehearing, page 4, first full paragraph) or an intent to cure the underlying condition (Id., paragraph bridging pages 4 and 5) underscores the need "to fashion claims that are precise, clear, correct, and unambiguous." In re Zletz, 893 F.2d at 1322, 13 USPQ2d at 1322.

"Consisting Essentially Of"

Applicants argue that claims 38, 40 through 42, 48, and 65 patentably distinguish over Saint-Leger in view of the transition phrase "consisting essentially of" (Request for



Rehearing, Section II., pages 5-9). According to applicants, the recitation of an active component in those claims "consisting essentially of" at least one 1-hydroxy-2-pyridone of formula (I) excludes the halogenated antibacterial agent disclosed by Saint-Leger. We disagree.

As stated in <u>PPG Indus., Inc. v. Guardian Indus. Corp.</u>, 156 F.3d 1351, 1355, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998),

By using the term "consisting essentially of," the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A "consisting essentially of" claim occupies a middle ground between closed claims that are written in a "consisting of" format and fully open claims that are drafted in a "comprising" format. (Emphasis added).

Here, applicants' argument that "consisting essentially of" excludes the halogenated antibacterial agent of Saint-Leger is an example of <u>ipse dixit</u> reasoning. Applicants do not describe the "basic and novel properties of the invention," or explain why or establish how the halogenated antibacterial agent of Saint-Leger materially affects those properties.

Additionally, it is apparent from applicants' specification (page 7, line 36 through page 8, line 16) that the composition of the claimed method may include a host of ingredients or additives. On this record, it is unclear why the halogenated antibacterial agent of Saint-Leger would "materially affect" the basic and novel properties of the invention and, accordingly, be excluded by the phrase "consisting essentially of;" whereas the host of ingredients listed in the specification do not materially affect the

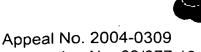
basic and novel properties of the invention and, accordingly, are included by the phrase "consisting essentially of." Applicants have not made it clear, in their specification or in their Request for Reconsideration, what they "regarded as constituting a material change in the basic and novel characteristics of the invention." <u>Id.</u>, 156 F.3d at 1355, 48 USPQ2d at 1355.

Matters Not Addressed in the Request for Rehearing

The appealed claims are not limited to a method of treating a human or animal patient in need of treatment for <u>patchy seborrheic dermatitis</u>, the classic, well-known disease with chronic recurrent legions (Exhibit A, page 8). In their Request for Rehearing, applicants do not deny that the term "seborrheic dermatitis" includes a disease spectrum; or that "[a] symptomatic, fluffy white dandruff of the scalp represents the mild end of the spectrum of seborrheic dermatitis and has been referred to as <u>pityriasis sicca</u>" (Exhibit A, page 8). Further, applicants do not deny that "[m]any cases of seborrheic dermatitis will respond to the same nonprescription drug regimen used to treat dandruff" (Exhibit C, page 550, column 2, lines 2 through 4).

Conclusion

In conclusion, for the reasons set forth, we adhere to our original decision vacating the examiner's final rejections of claims 38 through 42, 48, and 53 through 66; and entering new grounds of rejection under the provisions of 37 CFR § 41.50(b).



Having carefully reviewed applicants' Request for Rehearing, we decline to modify our original decision or opinion in any respect. Accordingly, the Request is denied.

DENIED

Sherman D. Winters

Administrative Patent Judge

BOARD OF PATENT

Demetra J. Mills

Administrative Patent Judge

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APPEALS AND

Lora Green

Administrative Patent Judge

) INTERFERENCES



Appeal No. 2004-0309 Application No. 09/077,194

Finnegan, Henderson, Farabow, Garrett & Dunner Franklin Square Bldg., Suite 700 1300 I Street, NW Washington, DC 20005-3315

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